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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61N 1/00	A1	(11) International Publication Number: WO 00/56394 (43) International Publication Date: 28 September 2000 (28.09.00)

(21) International Application Number: PCT/US00/07555

(22) International Filing Date: 22 March 2000 (22.03.00)

(30) Priority Data:
60/125,872 24 March 1999 (24.03.99) US

(71) Applicant (*for all designated States except US*): ALFRED E. MANN FOUNDATION [US/US]; P.O. Box 905, Santa Clarita, CA 91380-9005 (US).

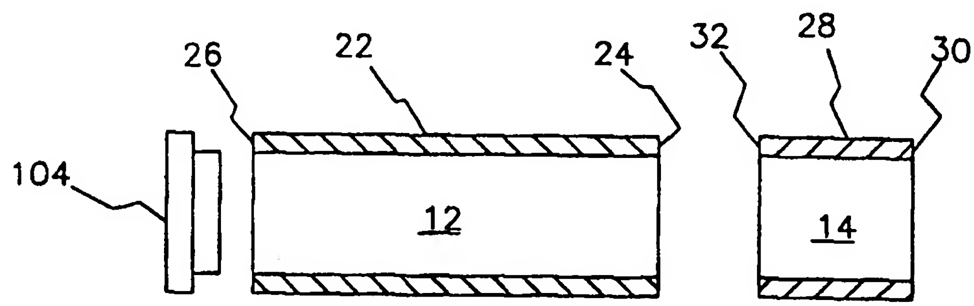
(71)(72) Applicant and Inventor: SCHULMAN, Joseph, H. [US/US]; 16050 Comet Way, Santa Clarita, CA 91351 (US).

(74) Agent: SEIDMAN, Abraham, N.; P.O. Box 905, Santa Clarita, CA 91380-9005 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: CERAMIC CASE ASSEMBLY FOR A MICROSTIMULATOR



(57) Abstract

A ceramic case assembly, and method of making a ceramic case assembly for a micro-stimulator includes the use of a cylindrical or tubular ceramic case (22). A metal band (28) is hermetically bonded to one end (24) of the ceramic case by brazing forming a ceramic case housing assembly for a micro-stimulator. In another embodiment, the metal band is jointed to the ceramic case with a step joint or angle joint for self-jigging. In another embodiment, a metal band is attached to each end of the ceramic case.

CERAMIC CASE ASSEMBLY FOR A MICROSTIMULATOR

This application claims the benefit of U. S. Provisional Application No. 60/125,872, filed March 24, 1999 and U. S. Provisional Application No. 60/126,531, filed March 26, 1999.

FIELD OF THE INVENTION

The present invention relates to a structure and method of manufacture of a ceramic case assembly for a microstimulator or microsensor for implantation in a living body, and more particularly to a ceramic case that is of a size and shape capable of implantation by expulsion through the lumen of a hypodermic needle.

BACKGROUND OF THE INVENTION

Simulators that are implanted in living bodies and powered from external sources must be housed in packages constructed of biocompatible materials. These packages must protect the electronic circuitry located within them from body fluids and ions so that the electronic circuitry can survive for extended periods of time without any significant changes in performance.

Today, the most commonly used metals for implantable packages are titanium, stainless steel and cobalt-chromium alloys. These metals are biocompatible and corrosion resistant. Normally, the package construction consists of parts that are welded together to insure hermeticity. However, where there is a need to inductively couple an alternating electromagnetic field to an internal pickup coil, the metal package becomes a hindrance. Specifically, transmission of power is substantially reduced by eddy currents generated in the metal package due to the alternating electromagnetic field. To solve that problem, receiving coils are often placed outside the metal package, increasing the size and complexity of the implanted device.

Electrical stimulation devices contain electrical components inside the package that are connected to stimulation leads by hermetic feedthrough, which permit the

flow of electrical currents through the package wall while maintaining hermeticity. Disadvantageously, each feedthrough is a possible leak path that can ruin the hermeticity of the package.

Glasses and ceramics represent viable materials for an implantable medical device package because they are transparent to alternating electromagnetic fields. Receiving coils can be placed inside a hermetic zone of a ceramic or glass package, creating an overall smaller and simpler implant device and reducing the possibility of coil failure due to saline leakage. Glasses and ceramics are inert and highly insoluble. which are favorable characteristics for long term implant materials.

Unfortunately, all known high sealing temperatures characterize biocompatible glasses and ceramics, which high temperatures may damage electronic components commonly included in electronic devices implanted in living bodies. Low-melting temperature glasses my not be used because they all have the property of being corroded by body fluids. Therefore, packages composed entirely of ceramic and/or glass have generally not been considered practical for implant applications. Also, because glasses and ceramics are inelastic, they are subject to fracture not only from mechanical shock but also from differential thermal expansion if even a moderate temperature gradient exists thereacross. Therefore, welding is not a practical method of sealing glass or ceramic materials. Instead, if a glass package is used, virtually the entire package and its contents must be raised to the high melting temperature of the glass, ceramic or metal braze that is used to effect a sealing of the glass or ceramic package. Such sealing methods are unsatisfactory.

One type of hermetically sealed ceramic and metal package is shown in U.S. Patent No. 4,991,582, issued to Byers, et al. and is incorporated herein by reference. A ceramic case and a metal band are hermetically sealed together, each being characterized by similar coefficients of linear thermal expansion. The electronic circuitry is then loaded inside the package, and soldering a metal header plate to the metal band effects final package closure.

A brazeless ceramic-to-metal bond for use in implantable devices is shown in U.S. Patent No. 5,513,793 issued to Malmgren and incorporated herein by reference.

The '793 patent describes a method and apparatus for forming a hermetically sealed bond between a ceramic case and a metal band. The ceramic case and the metal band are hermetically sealed together at elevated temperature and pressured. The ceramic and metal thus bonded are characterized by similar coefficients of linear thermal expansion.

The structure and method of manufacture of an implantable microstimulator are shown in U.S. Patent Numbers 5,193,539 and 5,193,540, both issued to Schulman et al. Both of these are incorporated herein by reference. These patents describe an implantable microstimulator which is substantially encapsulated within a hermetically sealed housing inert to body fluids. The housing is made of glass capillary tubing with electrodes exposed at each end, the electrodes being sealed to the glass tube with glass beads.

Unfortunately, the microstimulator shown in the '539 and '540 patents is difficult to manufacture; the external electrodes are fragile and require many welds to hermetically seal the package. These welds are done one at a time and are very time consuming. The joint between the glass case, glass beads and metal electrodes is also susceptible to leaking. Since the microstimulator case is made from glass, it is fragile and susceptible to cracking. Disadvantageously, glass is also transparent to light. Some components inside a glass package may be light sensitive and, if so, a light barrier must be provided, such as a film or mask covering the components to prevent undesired light from reaching the components.

Malmgren, Santogrossi, and Schulman show a method and apparatus of a strong metal-to-ceramic bond (U.S. Patent Application, serial no. 09/327,830, filing date: 03/24/1999).

In view of the above, it is evident that what is needed is a microstimulator package that is constructed from a material that is transparent to an alternating magnetic field. It must at the same time protect the electronic circuitry hermetically sealed therein. It must minimize the number of joints to be sealed, it must is not be prone to cracking or leaking, and it must be cost effective to manufacture.

SUMMARY OF THE INVENTION

The present invention advantageously addresses the needs above as well as other needs by providing an apparatus and method for manufacturing a ceramic case assembly for a microstimulator.

The ceramic case assembly of the present invention is inert to body fluids. The majority of the case is made of biocompatible ceramic material that is cylindrical in shape with open ends, i.e., tube-shaped. A closed metal band or ring is attached to one or both ends of ceramic case. The metal band is made from a biocompatible material that has the same coefficient of thermal expansion (CTE) as the ceramic material. The attachment of the metal band to the ceramic case can either be a butt joint or one of the components may have a fixturing ring, step or angle for self-jigging (with the other surface with the appropriate mate-able surface). The attachment also provided a hermetic seal. The preferred method of attachment is brazing the metal band to the ceramic case using a metal or metal alloy braze. Such brazing, while performed at a high temperature, is done without any electronic circuitry being present. It results in a hermetic seal. Once the brazing is done, the ceramic case assembly is ready for assembly with other components (i.e., electronic circuitry, ends caps) to make a hermetically sealed microstimulator. Welding the metal end cap to the metal ring completes the hermetic seal. Normally the weld is made about 0.100 inches away from the braze, with a heat sink, or heat sinks, in use so as to keep the braze from melting. Once thus assembled, the microstimulator with ceramic case is ready to be implanted in living body.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other aspects, features and advantages of the present invention will be more apparent from the following more particular description thereof, presented in conjunction with the following drawings wherein:

Figure 1 is a cross-sectional exploded view of a ceramic case housing assembly including a ceramic case and a metal band;

Figure 2a is a cross-sectional view of the ceramic case housing assembly

showing the ceramic case and the metal band assembled together with the subsequently inserted electronic circuit assembly;

Figure 2b is a cross-sectional view of the ceramic case housing assembly showing the ceramic case and the metal band assembled together with the subsequently inserted electronic circuit assembly together with the assembly second metal cap and showing the use of heat sinks;

Figure 3a is a partial cross-sectional view of another embodiment of Figure 2 showing an optional technique for attaching the metal band to the ceramic case using a step joint for self jigging;

Figure 3b is a partial cross-sectional view of another embodiment of Figure 2 showing a different optional technique for attaching the metal band to the ceramic case using two mate-able surfaces each at an appropriate to form a self jigging joint;

Figure 4 is a cross-sectional view of another embodiment of Figure 2 showing a metal band attached at each end of the ceramic case.

Figure 5 is a cross-sectional exploded view of a ceramic case housing assembly including a ceramic case and a metal band, two metal end caps, and two high temperature braze preforms in the shape of rings.

Below is a list of reference numbers associated with the figures.

No.	Component
10	Housing Assembly
12	Ceramic Case
14	Metal Band
18	Bonding Site
22	Wall of the Ceramic Case
24	Flat Annular Surface (Ceramic Case)
26	Flat Annular Surface (Ceramic Case)
28	Wall of Metal Ring
101	Electronic Circuit Assembly
102	High Temperature Braze
103	Metal Cap

201 High Temperature Braze Preform

202 High Temperature Braze Preform

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description of the presently contemplated best mode of practicing the invention is not to be taken in a limiting sense, but is made merely for the purpose of describing the general principles of the invention. The scope of the invention should be determined with reference to the claims.

Figures 1 and 2 show the construction of the ceramic case housing assembly 10. Referring first to Figure 1, a cross-sectional exploded view is shown of the components used in the housing assembly 10. These components included a ceramic case 12 and a metal band 14. Figure 2 is a cross-sectional view showing the assembled housing assembly 10. In Figure 2, the ceramic case 12 and the metal band 14 are joined together with a hermetically sealed bond, such as a metal or metal alloy braze (e.g., nickel and titanium braze, 30/70), shown as bonding site 18. Since braze bonding is done at temperatures (over 1000 °C) and pressures (over 100 PSI) that can damage electronic circuitry, this circuitry is only inserted into the housing assembly 10 only after the attachment of the metal band 14 to the ceramic case 12 is completed. The ceramic case 12 and the metal band 14 have similar diameters with a butt attachment. Figure 3a show another attachment method of the band 14 to the case 12 that could be used, such as a step for self-jigging. Figure 3b show another attachment method of the band 14 to the case 12 that could be used, such as a bezel for self-jigging. The approaches of both Fig. 3a and Fig. 3b make it possible to increase the braze distance to insure hermeticity while decreasing the wall thickness of the metal or ceramic part.

The ceramic case 12 is preferably made from biocompatible ceramic material, e.g., aluminum oxide or zirconium oxide. The case 12 is cylindrical in shape (i.e. a hollow tube) with openings at both ends. The diameter of the ceramic case 12 is typically about 2mm and the length is approximately 10 mm. The side wall 22 of the

ceramic case 12 terminates around the open ends forming flat annular surfaces 24 & 26 at each end. Since the ceramic is not transparent, it tends to protect internal components that are sensitive to light.

The metal band 14 is preferable made from a biocompatible metal and is cylindrical in shape with openings at both ends (i.e. a ring). The diameter of the metal band 14 is 2 mm in diameter and is at lease 1 mm in length, and preferable approximately 2.5 mm in length. The side wall 28 of the metal band 14 terminates at each of the open ends, forming flat annular surfaces 30 and 23, to which the flat annular surface 24 of the ceramic case 12 is ultimately bonded at bonding site 18 (as shown in Figure 2). The band 14 is made from biocompatible metal, e.g. titanium, stainless steel, tantalum, niobium and niobium-titanium alloys such as 45% niobium-55% titanium and cobalt-chromium alloys. A preferred embodiment uses, to make band 14, any metal or alloy that readily forms an instant oxide when heated, i.e., that readily oxidized when heated in an oxygen-containing atmosphere. Note that the ceramic, the metal and the braze are chosen, in a preferred embodiment, to have similar coefficients of thermal expansion (CTE) of between 8 and 9 $mm^3/°C$. This minimizes the risk of cracking when the ceramic case 12, metal band 14 and braze are bonded together at high temperatures and then cooled.

Figure 2a shows the assembled ceramic case housing assembly 10. Many well-known processes may be used to hermetically bond the metal band 14 to the end of the ceramic case 12 utilizing biocompatible sealing materials. Some of these methods are described in U.S. Patent No. 4,991,582 and 5,513,793, previously incorporated herein by reference.

In a preferred method of manufacturing the housing assembly 10, the brazing of the metal band 14 to the aluminum oxide ceramic case 12 is done with a nickel-titanium (NiTi) braze with 30%Ni-70%Ti. A best mode metal band, or ferrule, is one made of niobium. The brazing of a zirconium oxide ceramic case, including 3% yttrium as a best mode formulation, utilizes a braze of 50% Ni and 50% Ti, with the metal band, or ferrule, in a best mode, made from a 45% niobium-55% titanium alloy.

The brazing operation may be done in a production line operation to

manufacture more than one housing assembly 10 at a time. Since brazing 102, Figure 2a) temperatures may reach over 1000°C, any electronic circuitry assembly (see 101 in Figure 2a, 2b) for a microstimulator is inserted into the housing assembly 10 only after the bonding at such high temperature is completed. Figure 2b shows the use of heat sinks when attaching the second cap 103. The first cap, 104, is first attached to the case with a high temperature braze 102, before the insertion of the electronic circuit assembly 101.

Referring next to Figure 4, there is shown another embodiment of the present invention wherein a metal band 14 is attached at each end of the ceramic case. The metal bands are brazed to the ceramic case at bonding site 18. The attachment may either be a butt or step joint as previously described.

Figure 5 shows the use of braze preforms in the shape of rings (210, 202) sized to fit. These preforms may be of the braze 30% Ni –70% Ti, or other suitable brazes (in terms of coefficient of expansion and ability to form a hermetic seal). In Figure 5, 104 is a metal cap, 12 is a ceramic cylinder, and 14 is a metal cylinder.

While the invention herein disclosed has been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.

CLAIMS

What is claimed is:

1. A ceramic case assembly for a microstimulator comprising:

a cylindrical ceramic case having at least one open end for receiving a temperature sensitive device such as an electronic circuit assembly of a microstimulator; and

a closed annular metal band hermetically bonded to the other end of the ceramic case, the band being formed from a metal having a coefficient of thermal expansion substantially the same as that of the ceramic case.

2. The ceramic case assembly of claim 1 wherein the annular metal band is hermetically bonded to one open end of the ceramic case by a metal or metal alloy braze.

3. The ceramic case assembly of claim 1 wherein the metal or metal alloy braze is such that it has a coefficient of thermal expansion substantially the same as that of the ceramic case and the closed annular metal band.

4. The ceramic case assembly of claim 2 wherein the metal braze is 30% nickel and 70% titanium for a ceramic case of aluminum oxide.

5. The ceramic case assembly of claim 4 wherein the closed metal band is niobium.

6. The ceramic case assembly of claim 2 wherein the metal braze is 50% nickel and 50% titanium for a ceramic case of zirconium oxide.

7. The ceramic case assembly of claim 6 wherein the closed metal band is an alloy of 45% niobium-55% titanium.

8. The ceramic case assembly of claim 2 wherein the metal braze is 50% nickel and 50% titanium for a ceramic case of zirconium oxide and 3% yttrium.

9. The ceramic case assembly of claim 8 wherein the closed metal band is an alloy of 45% niobium-55% titanium.

10. The ceramic case assembly of claim 1 wherein the open end of the ceramic case and the metal band butt against each other during bonding forming a butt joint.

11. The ceramic case assembly of claim 1 wherein the open end of the ceramic case and the metal band are shaped according to a form chosen from the group consisting of stepped, or angled, with the appropriate opposing mate-able surface to define a self-jigging junction between the ceramic case and the metal band during bonding forming a step joint or angle joint.

12. The ceramic case assembly of claim 1 wherein the ceramic is an inert ceramic selected from the group consisting of aluminum oxide, zirconium oxide and zirconium oxide with 3% yttrium and wherein the metal comprising the metal band is selected from the group consisting of titanium, stainless steel, tantalum, niobium, niobium-titanium alloys, and cobalt-chromium alloys.

13. The ceramic case assembly of Claim 12 wherein the niobium-titanium metal alloy is 45% niobium-55% titanium.

14. A ceramic case assembly for a microstimulator comprising:
a cylindrical ceramic case having open ends for receiving an electronic circuit assembly of a microstimulator; and

a pair of closed annular metals bands hermetically bonded to each open end of

the ceramic case, the bands being formed from a metal having a coefficient of thermal expansion substantially the same as that of the ceramic case.

15. The ceramic case assembly of claim 14 wherein the annular metal bands are hermetically bonded to both open ends of the ceramic case by a metal or metal alloy braze.

16. The ceramic case assembly of claim 15 wherein the metal or metal alloy braze is such that it has a coefficient of thermal expansion substantially the same as that of the ceramic case and the closed annular metal bands.

17. The ceramic case assembly of claim 15 wherein the metal alloy braze is 30% nickel and 70% titanium for a ceramic case of aluminum oxide.

18. The ceramic case assembly of claim 17 wherein the metal bands are niobium.

19. The ceramic case assembly of claim 15 wherein the metal braze is 50% nickel and 50% titanium for a ceramic case of zirconium oxide.

20. The ceramic case assembly of claim 19 wherein the metal bands are an alloy of 45% niobium-55% titanium.

21. The ceramic case assembly of claim 15 wherein the metal braze is 50% nickel and 50% titanium for a ceramic case of zirconium oxide and 3% yttrium.

22. The ceramic case assembly of claim 21 wherein the metal bands are an alloy of 45% niobium-55% titanium.

23. The ceramic case assembly of claim 15 wherein the open ends of the ceramic case and the metal bands butt against each other during bonding forming a butt joint.

24. The ceramic case assembly of claim 15 wherein the open ends of the ceramic case and the metal bands are shaped according to a form chosen from the group consisting of stepped, or angled, with the appropriate opposing mate-able surface to define a self-jigging junction between the ceramic case and the metal band during bonding forming a step joint or angle joint.

25. The ceramic case assembly of claim 15 wherein the ceramic is an inert ceramic selected from the group consisting of aluminum oxide, zirconium oxide and zirconium oxide with 3% yttrium and wherein the metal comprising the metal band is selected from the group consisting of titanium, stainless steel, tantalum, niobium, niobium-titanium alloys, and cobalt-chromium alloys.

26. The ceramic case assembly of Claim 25 wherein the niobium-titanium metal alloy is 45% niobium-55% titanium.

27. A method of forming a ceramic case assembly for a microstimulator comprising the steps of:

positioning a cylindrical ceramic case against one or more metal bands, the ceramic case consisting of a first material and the metal bands consisting of a second material;

sealing the ceramic case and each of the metal band(s) to the ceramic case, hermetically; and

maintaining a tube-like structure for the assembly.

28. The method for the ceramic case assembly of claim 27 further comprising the steps of

selecting the first material as an inert ceramic selected from the group consisting of aluminum oxide, zirconium oxide and zirconium oxide with 3% yttrium; and

selecting the second material as a metal material selected from the group consisting of titanium, stainless steel, tantalum, niobium, niobium-titanium alloys, and cobalt-chromium alloys.

29. The method for the ceramic case assembly of claim 27 further comprising the step of selecting the second material (of the metal bands) made from the materials having a coefficient of thermal expansion substantially the same as that of the first material (of the ceramic case).

30. The method for the ceramic case assembly of claim 27 further comprising the step of hermetically sealing the joint of said ceramic case and said metal band using a metal or metal alloy braze.

31. The method for the ceramic case assembly of claim 30 further comprising the step of selecting the metal or metal alloy braze such that it has a coefficient of thermal expansion substantially the same as that of the ceramic case and the closed annular metal band.

32. The method for the ceramic case assembly of claim 31 further comprising the step of utilizing a metal alloy braze wherein said braze is 30% nickel and 70% titanium for a ceramic case of aluminum oxide; and wherein said braze is 50% nickel and 50% titanium for a ceramic case of zirconium oxide and for a case of zirconium oxide with 3% yttrium.

33. The method for the ceramic case assembly of claim 32 wherein the metal band material is niobium when the ceramic is aluminum oxide and is an alloy of 45% niobium-55% titanium.

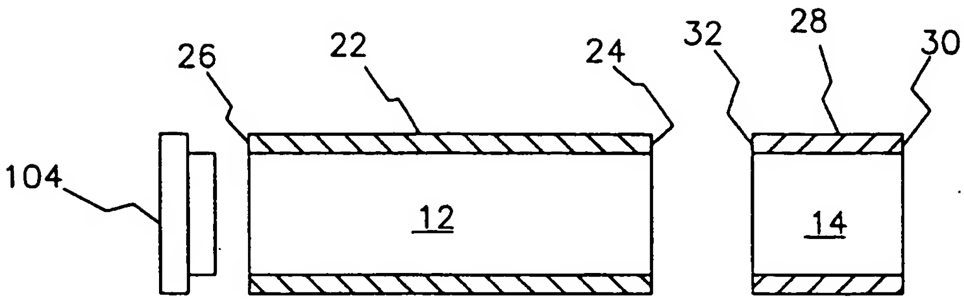


FIGURE 1

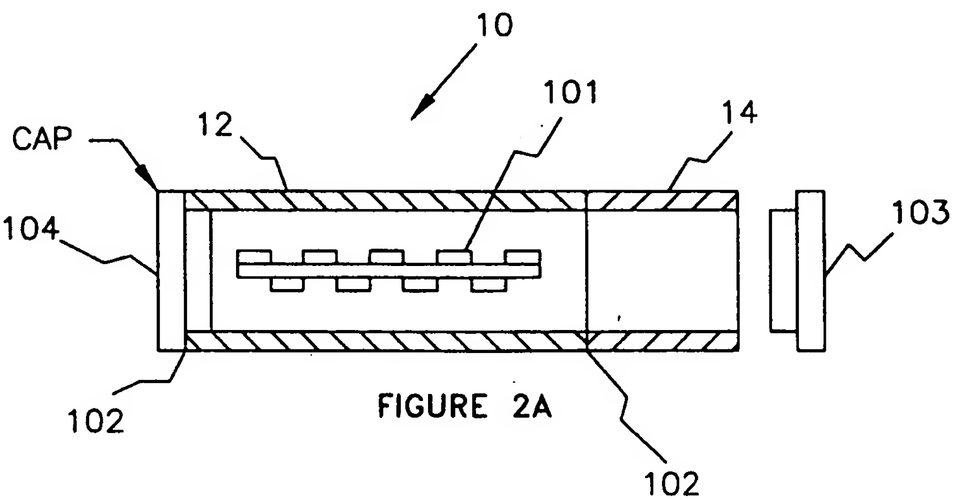


FIGURE 2A

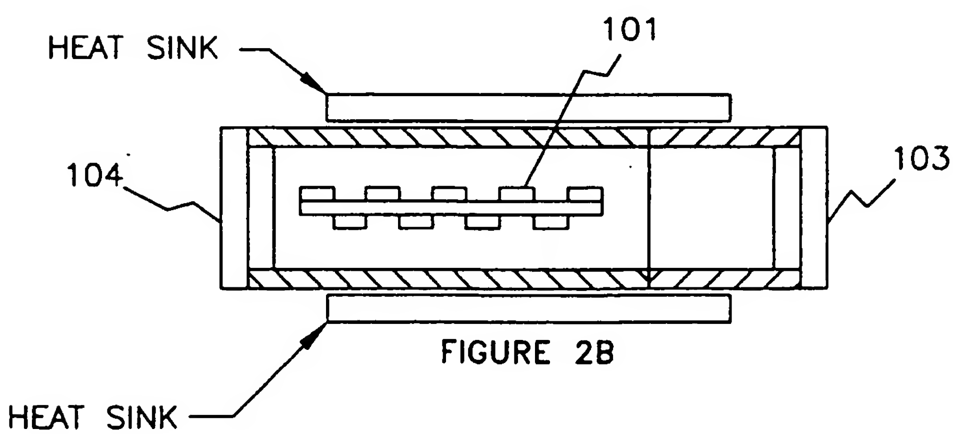


FIGURE 2B

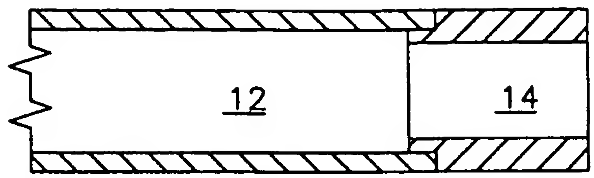


FIGURE 3A

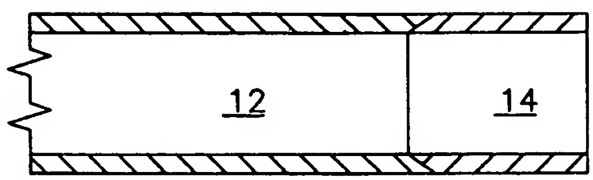


FIGURE 3B

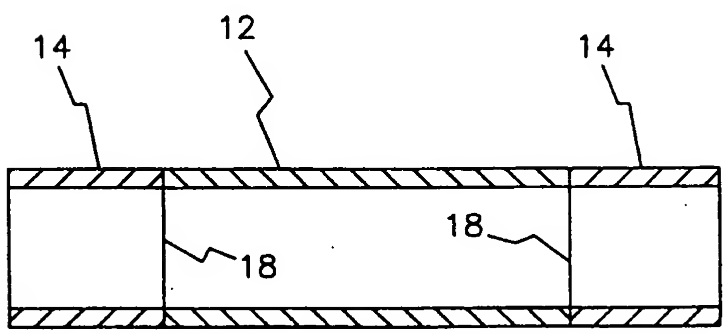


FIGURE 4

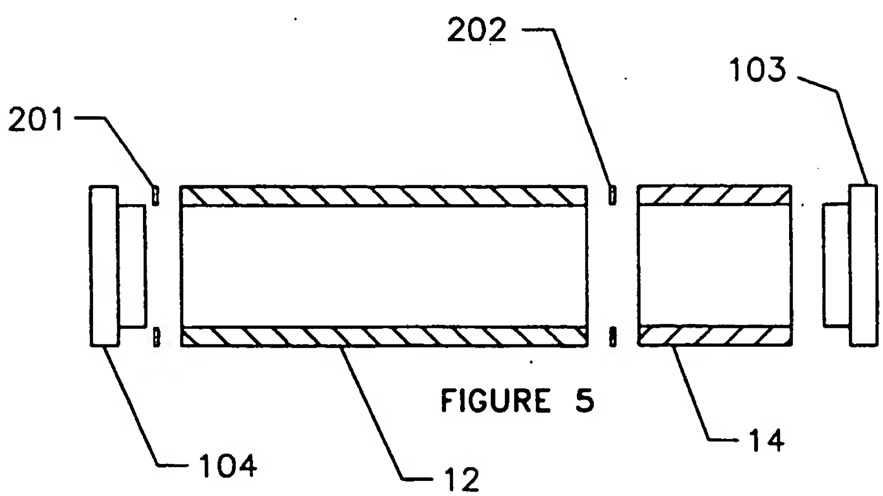


FIGURE 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/07555

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61N 1/00
US CL : 607/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 29/592, 825; 607/1, 2, 5, 9, 36, 46, 48, 50, 51

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,785,827 A (FISCHER) 22 November 1988, entire document.	1-3, 10, 12, 27-31 --- 4, 5, 11, 32
Y	US 4,991,582 A (BYERS et al.) 12 February 1991, entire document.	4, 5, 11, 32

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search	Date of mailing of the international search report
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Facsimile No. (703) 305-3230	Telephone No. (703) 308-2612